EXHIBIT 4
FILED UNDER SEAL

CONFIDENTIAL

EXPERT REPORT

Analysis of Distributor Regulatory Compliance to Maintain Effective Controls for the Prevention of Diversion of Controlled Substances on behalf of the City of Huntington and Cabell County, West Virginia

---

Prepared by
James E. Rafalski
37637 Five Mile Road #278
Livonia, MI 48154

I. QUALIFICATIONS AND EXPERIENCE

A. Statement of Qualifications

- 1999 graduate of Eastern Michigan University with a degree in Public Administration.
- 26 years of law enforcement experience.
- Retired in 2002 as an Executive Lieutenant with the Romulus Police Department.
- Drug Enforcement Administration Diversion Investigator assigned to the Detroit Divisional Office from September 2004 through retirement in June 2017. Diversion Investigators are responsible for several different types of investigations including regulatory investigations, state-action related investigations, pre-registration application investigations, civil investigations, administrative investigations, and criminal investigations. In 2011 Detroit DEA management restructured the responsibilities of the diversion investigators in the Detroit Divisional Office. At that time, Mr. Rafalski's primary responsibility was to conduct administrative, civil, and regulatory investigations of DEA registrants.
- Successfully completed the following DEA training: Basic Diversion Investigator School (2004), Distributor Briefing/Training (2008), Advanced Diversion Investigator School (2009), Comprehensive Regulatory Investigation Training (2010), Diversion Leadership School (2011), Advanced Diversion Investigator School (2015).
- Participated as a DEA Instructor in the design and presentation of the following training programs: Task Force Officers Training and Orientation, Detroit, Michigan (January 2009), Basic Narcotics Training, Macomb Police Academy, Clinton Township, Michigan (April 2009), U.P. Prescription Diversion/Asset Forfeiture Class, Marquette, Michigan (July 2009 and September 2010), and Basic Narcotic Investigator Course, Richmond, Kentucky (May 2010). Prescription Drug Diversion, Gaylord, Michigan (2015)

B. Awards

- Maintained a performance rating of "Outstanding" from 2005 to 2016.
- Received DEA performance awards from 2009 to 2015 and in 2017.
- Received an award from the Detroit Federal Executive Board in 2013 for exemplary public service to the DEA.

chargeback data, customer files, internal and external communications to include emails, written correspondence, and notes.

- Administrative investigation resulted in an Administrative Memorandum of Agreement that remained in effect for three years.

As a DEA Diversion Investigator with 13 years of experience (2004-2017), I am uniquely qualified to offer expert opinions regarding compliance with federal regulations governing the distribution of controlled substances including oxycodone and hydrocodone. I am familiar with the DEA Diversion Investigators Manual and received training from the United States Department of Justice suspicious order monitoring, data analysis from ARCOS, reporting of suspicious orders and the due diligence required before shipping an order flagged as suspicious. I directly participated in the successful prosecution of Masters Pharmaceutical which resulted in a case opinion from the highest federal court in the country (to date). I led the first action that led to a memorandum of agreement with a manufacturer for failure to maintain effective controls to prevent diversion and failing to design and operate an adequate suspicious order monitoring system.

Based (a) on my education, training and experience, (b) the law, regulation and practices in the area of CSA enforcement, and (c) on my review of document and testimony provided in this case (MDL 2804), I am of the opinion to a reasonable degree of professional certainty that there was a systematic, prolonged failure over many years by the defendant distributors to maintain effective controls against diversion of legitimate opioid prescriptions into the illicit market.[1] I am further of the opinion that this systematic failure was a substantial cause of the opioid epidemic plaguing the country and specifically in Cabell County and the City of Huntington, West Virginia. I am prepared to testify regarding the regulatory duties imposed by the CSA and federal regulations. I have been asked to review the documents produced by the defendants and depositions taken and offer opinions regarding statutory and regulatory compliance.

I offer my opinions herein to a reasonable degree of professional certainty. I believe the facts stated herein are true and accurate and based on the record provided to me. I understand that the defendants continue to supplement discovery and have disclosed tens of millions of documents. I have relied upon the defendant's answers to Combined Discovery Requests as a basic outline for evidence of compliance to reach my opinions.

I am being compensated at the rate of $300.00 per hour for the time I have spent related to this report. The hourly rate for my time spent testifying is $500.00 per hour. I have previously provided expert testimony by deposition in *In re: National Prescription Opiate Litigation*, MDL No. 2804 (Case Track One) and in the New York State litigation, *In re Opioid Litig.*, Index No. 400000/2017. I have not authored any publications or articles. In addition to the documents and testimony cited within my report, I have also reviewed documents identified in the attached Schedule I.

[1] I provide all opinions in this report with a reasonable degree of professional certainty.

pharmacy or buyer should not ship until an investigation of the initial suspicious order occurs, because there is an outstanding concern about the past shipment that has not been addressed. Otherwise, a distributor is potentially sending larger and larger quantities of controlled substances to a buyer that is under suspicion of being a diversion risk. The suspicious order monitoring system failures described above directly led to massive quantities of pills being shipped to buyers who had placed suspicious orders of controlled substances. These orders never should have shipped until after the suspicion of diversion was dispelled.

IV. Identifying Suspicious Orders Distributed in the City of Huntington and Cabell County, West Virginia

I have described in this report the ways in which Cardinal Health, McKesson, and AmerisourceBergen's inadequate response to their statutory and regulatory requirements to maintain effective controls related to the sales of prescription opioids would potentially cause the diversion of these pills for non-medical use. I have reviewed six suspicious order methodologies, some of which were utilized by one or more of the defendants. These methodologies are identified in the Report of Craig J. McCann as "Maximum Monthly, Trailing Six-month Threshold," "Trailing Six-month Maximum Monthly, Fixed After First Triggered Threshold," "Twice Trailing Twelve-month Average," "Three Times Trailing Twelve-month Average," "Maximum 8,000 Dosage Units Monthly," and "Maximum Daily Dosage Units." The purpose of each system was to identify suspicious orders that should not have been shipped unless the distributors' due diligence eliminated the suspicion of diversion.

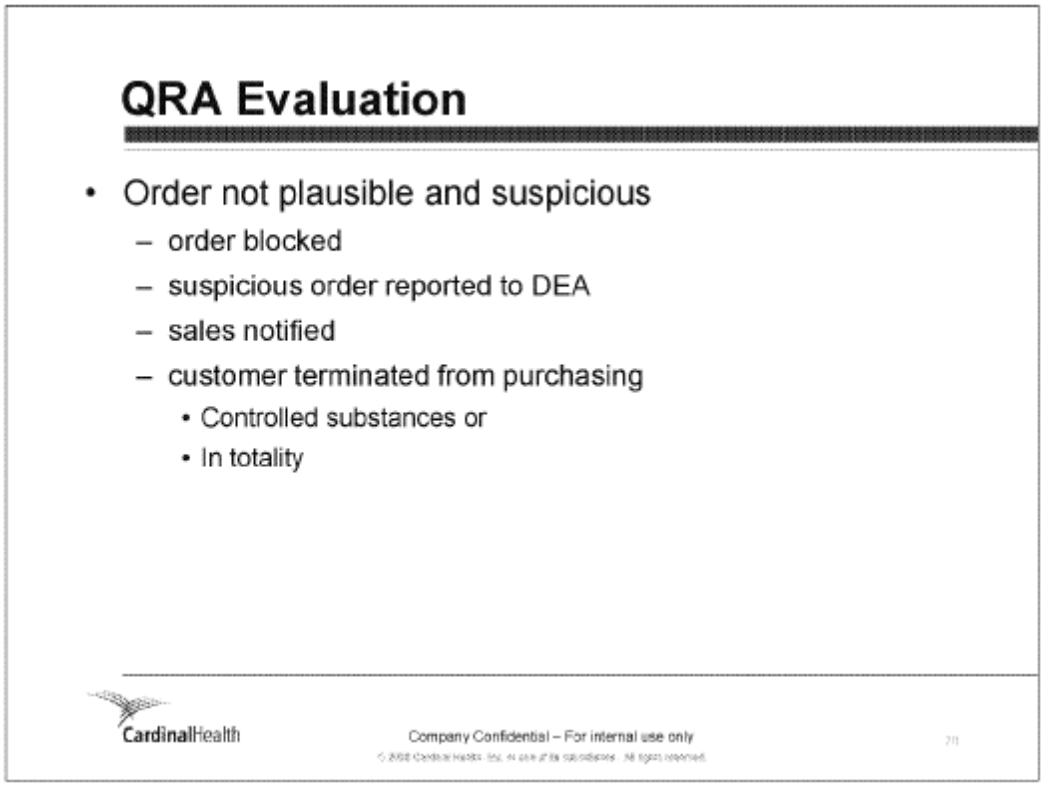
With the exception of the method titled Trailing Six-month Maximum Monthly, Fixed After First Triggered Threshold,[116] under each of these methodologies, once an order by a pharmacy is flagged and the distributor does not conduct sufficient due diligence to dispel the suspicion of diversion, each subsequent order by that pharmacy is also flagged. The failure to conduct adequate due diligence on the initial triggering order, means that all subsequent orders by that pharmacy are likewise suspicious. This is consistent with the testimony of Thomas Prevoznik who testified on behalf of the DEA that distributors should not ship a suspicious order and should terminate all future sales to that same customer until they can rule out that diversion is occurring.[117] This is also consistent with Cardinal Health's statement in *Cardinal Health, Inc. v. Holder*, 1:12-cv-00185, that "as early as 2009" Cardinal's policy was to "terminate controlled-substance sales to the customer and report the termination to DEA" if the "customer's order could not be filled because it was suspicious[.]"[118] Cardinal also trained its people on this very same approach. The slide below is from one of Cardinal's training presentation in which they indicate that if a

[116] Under the Trailing Six-month Maximum Monthly, Fixed After First Triggered Threshold, when a transaction causes the number of dosage units shipped to a pharmacy in a month to exceed the highest number of dosage units shipped to the pharmacy in any one of the six preceding months, the dosage units of highest month in the preceding six months becomes threshold which is then applied in all subsequent months.

[117] Depo. of Thomas Prevoznik (Vol. II), 627:7-629:15.

[118] CAH_MDL_PRIORPROD_DEA12_00014702, 719.

suspicious order is triggered it should be reported and the customer would be cut off altogether, or at least from purchasing controlled substances.[119]



McKesson likewise stated in its SMP Operations Manual that its policy was to cease all controlled substance sales to a customer once an order by that customer was deemed suspicious.[120]

Each method would have identified a significant volume of orders of opiates as shown in the tables below.

Cabell County and City of Huntington: 1996-2018[121]

A. Maximum Monthly, Trailing Six-month Threshold

	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen	11,610,920 (90.6% of total dosage units)	20,621,360 (91.1% of total dosage units)

[119] CAH_MDL2804_00227518, 587.

[120] MCKMDL00409224, 239.

[121] McCann Report, App. 7.

Cardinal Health	15,997,400 (93.1% of total dosage units)	14,795,350 (82.5% of total dosage units)
McKesson	3,501,970 (87.9% of total dosage units)	3,261,250 (87.4% of total dosage units)

B. Trailing Six-month Maximum Monthly, Fixed After First Triggered Threshold

	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen	3,763,580 (29.4% of total dosage units)	5,616,380 (24.8% of total dosage units)
Cardinal Health	11,325,200 (65.9% of total dosage units)	7,252,580 (40.5% of total dosage units)
McKesson	805,300 (20.2% of total dosage units)	2,390,800 (64.0% of total dosage units)

C. Twice Trailing Twelve-month Average

	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen	10,477,680 (81.8% of total dosage units)	18,877,140 (83.4% of total dosage units)
Cardinal Health	14,011,880 (81.5% of total dosage units)	16,593,780 (92.6% of total dosage units)
McKesson	2,405,620 (60.4% of total dosage units)	2,362,420 (63.3% of total dosage units)

D. Three Times Trailing Twelve-month Average

	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen	8,360,740 (65.3% of total dosage units)	15,701,930 (69.4% of total dosage units)
Cardinal Health	9,567,580 (55.7% of total dosage units)	14,957,360 (83.5% of total dosage units)

McKesson	1,005,320 (25.2% of total dosage units)	1,245,640 (33.4% of total dosage units)

E. Maximum 8,000 Dosage Units Monthly

	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen	10,446,280 (81.5% of total dosage units)	21,679,760 (95.8% of total dosage units)
Cardinal Health	13,274,080 (77.2% of total dosage units)	16,159,150 (90.2% of total dosage units)
McKesson	2,098,560 (52.7% of total dosage units)	2,484,640 (66.6% of total dosage units)

F. Maximum Daily Dosage Units

	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen	12,459,020 (97.3% of total dosage units)	22,582,020 (99.8% of total dosage units)
Cardinal Health	16,527,880 (96.2% of total dosage units)	17,688,100 (98.7% of total dosage units)
McKesson	3,713,000 (93.2% of total dosage units)	3,648,650 (97.7% of total dosage units)

I have been asked to identify the number of opioid pills that entered Huntington and Cabell County unlawfully. This is an impossible task due to the defendants' failure to comply with their Federal statutory and regulatory requirements.[122] However, it is my opinion to a reasonable degree of professional certainty that applying the test set forth in *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (2017) provides a reasonable estimate and an initial trigger and first step to identifying orders of unusual size.[123] *See* Methodologies A and B above. Pursuant to *Masters*, "as a matter of common sense and ordinary language, orders that deviate

[122] This includes, but is not limited to, the requirement of the defendants to maintain effective controls against diversion, the reporting requirement, and the not shipping requirement. The detail of some of these failures is set out more completely below in the Distributor-specific sections of this report.

[123] This approach does not take into consideration unusual pattern or frequency.

from a six-month trend are an 'unusual' and not 'normal' occurrence" *Id.* at 216. I further opine that the controlled substances identified by the application of this algorithm would more likely than not be diverted from its intended use.

Based on my education, background, and experience, as well as my review of relevant documents, the absence of adequate distributor due diligence and failure to respond to indicators of suspicious orders as described in this report constitutes the Defendants' failures to comply with the requirements of the Controlled Substances Act. It is my opinion that this misconduct led to the excess quantity of opiate pills flooding the illicit market in Huntington and Cabell County. Methodologies A and B above are designed to identify orders of "unusual size" pursuant to 21 CFR 1301.74(b). Therefore, by definition, the orders identified by these methodologies are suspicious under the Controlled Substances Act and must be reported to the DEA. I have seen no evidence in the Defendants' productions provided to me that the Defendants conducted adequate due diligence on the orders identified in Methodologies A and B or reported the orders to the DEA as required by law. It is foreseeable that failing to comply with the Controlled Substances Act, specifically 21 U.S.C. § 823 et al., and 21 C.F.R. 1301.74, enables the diversion of controlled substances.[124] Congress has also declared that "[t]he illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people."[125] Based on my education, background, and experience, it is my opinion, to a reasonable degree of professional certainty, that the pills identified in Methodology A and B were more likely than not diverted and used for an illicit purpose.

My opinion on diversion is also supported by and consistent with other evidence in this case. West Virginia has the highest drug overdose death rate in the country.[126] Jan Rader, Chief of the City of Huntington Fire Department, testified that people she has seen responding to overdose calls have told her that their use of opioid pills began with prescription pills obtained with a legal prescription and then moved to buying pills illegally.[127] While Chief Rader testified that she sees all sorts of "prescription" opioids in her role, the most common types of opioids she sees on the street are hydrocodone and oxycodone.[128] Captain Rocky Johnson, who worked for the Huntington Police Department for 28 years, focused on drug-related crimes from 2012 until his retirement in 2019, found that one of the primary illegal drugs he was seeing on the street in

[124] Prevoznik Depo. (Vol. II), 642:3-643:1.

[125] 21 U.S.C. § 801(2).

[126] United States, Congress, House, Committee on Energy and Commerce. *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*, December 19, 2018, p. 4 (available at https://republicans-energycommerce.house.gov/wp-content/uploads/2018/12/Opioid-Distribution-Report-FinalREV.pdf) (last visited August 3, 2020).

[127] Depo. of Rader, 32:7-19.

[128] Depo. of Rader, 68:3-22.